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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,317

01/27/2004

M. Peter Marinkovich

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/766,317	MARINKOVICH, M. PETER	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 13-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-11,13-35 are pending.

Claim 8-11, 13-35 have been withdrawn.

Claims 1-7 are under currently under examination.

#### ***35 USC § 112 1<sup>st</sup> paragraph rejection maintained***

The rejection of claims 1-7, for failing to comply with the written description requirement is maintained.

Applicants argue that the genus of antibodies is supported by the written description of the instant application.

Applicants' arguments have been fully considered but they are not persuasive. The written description rejection was made to the antibodies against the **genus of migration facilitating proteins (MFPs)**. Claim 1 is interpreted as being drawn to an antibody against a genus of MFPs in the peptide consisting of amino acid 1399 to 1713 of SEQ ID NO:21, a 315 amino acid peptide. The specification defines "MFPs" as proteins that are capable of supporting migration of nearby tissue or tissue located at distal points in the body by neoplastic epithelial cells. The specifications discloses 3 defined MFPs (MFP5, 6 and 8) and a number of undefined MFPs (see Figs. 1A-D). MFPs can from 8 to 315 amino acids (see paragraph 81-83). The specification defines MFPs as proteins that are capable of supporting migration of nearby tissue or tissue located at distal points in the body by neoplastic epithelial cells. MFPs can be 8 to 315 amino acids (see paragraph 081-083). The specification states that MFPs encoding other subdomains within the laminin 5 alpha 3 G4 and/or 5 domains can also be generated and used in the methods of the present invention (paragraph 004). Thus, the genus of MFPs include a vast number of peptides that vary in length from 8 to 315 amino acids. The genus of MFPs encompasses a myriad of peptides and peptide conjugates. There is no structural similarity between the genus of MPPs as defined in the specification. The genus includes peptides which have no sequence similarity to other peptides within the genus. Thus, the genus of MFPs is not supported by the

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written description of the instant specification. Deleting the term "migrating facilitating protein" from claim 1 or replacing the term "migrating facilitating protein" with the term "an epitope in the human laminin 5 alpha 3 G4-5 domain" would obviate this rejection.

***35 USC § 102(b) rejections maintained***

The rejection of claims 1-4 and 7 under 35 USC 102(b) as being anticipated by Carter et al is maintained.

Applicants argue that Cater et al disclose antibodies that bind to the E170 band of the epilgrin complex or to the E36 band and would not bind to the G4/G5 domain.

Applicant's arguments have been fully considered but they are not persuasive. Carter et al disclose the production of polyclonal antibodies to the extracellular matrix of human foreskin keratinocytes (Example 2) which would comprise antibodies that would bind to the G4 subdomain lying between amino acid 1358 and amino acid 1366, the G4 subdomain lying between amino acid 1375 and amino acid 1390, and the G4-5 subdomain lying between amino acid 1399 and amino acid 1713.

***35 USC § 102(b) rejections withdrawn***

The rejection of claim 6 under 35 USC 102(b) as being anticipated by Carter et al is withdrawn in view of the amendment to claim 1 and Applicants arguments.

**NEW REJECTION: Based on amendment.**

**Claim Objections**

Claims 2 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to an antibody that specifically binds an epitope lying between amino acid 1399 and

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amino acid 1713 of SEQ ID NO:21. Claim 2 is drawn to an antibody that specifically binds an epitope lying between amino acid 1375 and amino acid 1390 of SEQ ID NO:21. Claim 4 is drawn to an antibody that specifically binds an epitope lying between amino acid 1358 and amino acid 1366 of SEQ ID NO:21. The epitopes described in claim 2 and 4 are outside the range of amino acids for the epitope recited in claim 1 for which claims 2 and 4 depend.

### ***Summary***

Claims 1-7 stand rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

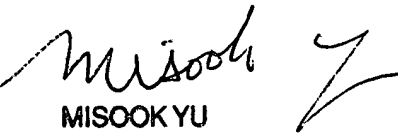
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the

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Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER